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NEWS RELEASE
Committee on Energy and Commerce

Rep. John D. Dingell, Chairman

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Contact: Jodi Seth or Alex Haurek, 202-225-5735

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Last week, after newly released data from a clinical trial suggested that Vytorin is no more effective than components of the drug that are generically available, both the American College of Cardiology (ACC) and the American Heart Association (AHA) issued statements questioning whether the clinical trial, the ENHANCE study, is sufficient to fairly

assess the effectiveness of Vytorin.

“Given the AHA’s and ACC’s recent statements on Vytorin and the ENHANCE study, our Committee is interested to learn what financial arrangements exist between the marketers of Vytorin and these two organizations,” Dingell said. “The public places great trust in the official views of the AHA and the ACC, so it is important to verify that these views have not been compromised by a financial relationship with the pharmaceutical industry.”

“The American Heart Association and the American College of Cardiology are widely perceived as objective and impartial, and are trusted by doctors and patients alike,” Stupak said. “Our Subcommittee intends to examine exactly how much funding these two organizations receive from Merck and Schering-Plough, how they use this funding and any potential conflicts of interest.”

In letters sent today to the American College of Cardiology, the American Heart Association, the Schering Plough Corporation and Merck & Co., Dingell and Stupak noted that Merck and the ACC foundation jointly sponsor six cardiologists for one year to conduct cardiovascular research. According to ACC’s website, the Merck Company Foundation has underwritten the entire program, investing million of dollars over the past 25 years. Merck/Schering-Plough also sponsors AHA’s Cholesterol website and is the only listed sponsor on the AHA’s cholesterol education page.

The Committee on Energy and Commerce began an investigation into the ENHANCE trial on December 11, 2007. The investigation was launched following concerns that, although the ENHANCE trial ended in April 2006, the data had not yet been released. The ENHANCE study compared the brand-name drug Vytorin to the generic drug simvastatin, both of which are used to treat patients with high-cholesterol. The study results show that Vytorin, which is a combination of Zetia and the generic simvastatin, resulted in no significant difference when compared to simvastatin alone.

The results of the ENHANCE study were released on January 14, 2008. Since then, Dingell and Stupak requested additional information about Vytorin and the ENHANCE study trial from Schering-Plough Corporation and Merck & Co, Inc., the Food and Drug Administration (FDA), and the Centers for Medicare and Medicaid Services (CMS).

Letter to American Heart Association »

Letter to American College of Cardiology »

Letter to Schering-Plough Corporation and Merck & Co., Inc. »

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Prepared by the Committee on Energy and Commerce

2125 Rayburn House Office Building, Washington, DC 20515